SECTION 5
510(k) SUMMARY (CONT.)

510(k) Notification K111338

GENERAL INFORMATION

AUG 1 1 2011

Applicant:

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U.S.A.
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Date Prepared: May 10, 2011

DEVICE INFORMATION

Trade Name:

Wildcat Catheter

Generic/Common Name:

Catheter, Percutaneous

Classification:

21 CFR§870.1250, Percutaneous catheter

Product Code:

DQY

SECTION 5
510(k) SUMMARY (CONT.)

PREDICATE DEVICE(S)

- Avinger Wildcat 6F Guidewire Support Catheter (K102022)
- LuMend Frontrunner® CTO Catheter (K033535)
- FlowCardia Crosser System (K072776)

INTENDED USE

The Wildcat Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Wildcat Catheter is contraindicated for use in the iliac, coronary, cerebral or carotid vasculature.

PRODUCT DESCRIPTION

The Wildcat Catheter is a sterile, single-use, disposable catheter designed to cross chronic total occlusions (CTOs) and to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions in the peripheral vasculature.

The Wildcat Catheter consists of the distal tip, catheter shaft, and proximal handle that allows for manual device manipulation and a means for flushing the catheter lumen. The catheter is 6F guide compatible, 110 cm long, and intended for use with 0.035" guidewires. Two key elements of the device define the treatment modality – the distal tip and the bilateral wedges. Both elements are visible through fluoroscopy and allow for CTO crossing and facilitation of guidewire placement.

Subsequent to conventional guidewire placement, atherectomy devices, PTCA catheters, and/or stents may be used to provide therapeutic benefit.

SUBSTANTIAL EQUIVALENCE

The Wildcat Catheter is substantially equivalent to the Wildcat 6F Guidewire Support Catheter, the LuMend Frontrunner® CTO Catheter, and the FlowCardia Crosser System. The subject device and the predicate devices are peripheral percutaneous catheters. The subject device and the Wildcat 6F Guidewire Support Catheter are identical in design, manufacturing, operation, and material composition. The proposed indications for use for the subject device is substantially equivalent to the indications for use for the LuMend Frontrunner® CTO Catheter and the FlowCardia Crosser System. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Wildcat Catheter is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary nonclinical and clinical testing was conducted to support a determination of substantial equivalence to the predicate devices.

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Nonclinical Testing Summary:

The Wildcat Catheter performance characteristics were evaluated in the following in vitro and in vivo studies.

- Visual and Dimensional Verification
- Tensile Testing
- Torque Testing
- Guidewire advancement
- Device Advancement
- Tip Deflection
- Device leak testing
- Luer Leak Testing
- Slider Force Testing
- Flexibility/Trackability
- Spiral Blade Functional Testing
- Tip Deflection Testing
- Coating Friction Testing
- Biocompatibility
- In Vitro Simulated Use Testing
- Device Evaluation in Porcine Model
- Packaging Testing
- Shipping Testing
- Sterility Testing
- Shelf Life Testing

The collective results of the nonclinical testing demonstrate that the Wildcat Catheter meets the established specifications necessary for consistent performance for its intended use. In addition the testing demonstrates that the Wildcat Catheter does not raise new questions of safety or effectiveness when compared to the predicate devices.

Clinical Testing Summary:

A multi-center, prospective, non-randomized study (CONNECT Study) was conducted to evaluate the safety and effectiveness of the Wildcat Catheter used to cross chronic total occlusions in the superficial femoral and popliteal arteries. Subjects were followed through 30-days post procedure.

The Wildcat Catheter was used in 84 subjects enrolled in the study from 15 sites in the United States. The patient population consisted of those presenting with Peripheral Artery Disease who met all eligibility criteria, including documented Rutherford Classification ranging from 2-5 and angiographic evidence of 99-100% stenosed femoropopliteal arteries that were $\geq$ 1 cm and $\leq$ 30 cm in length. Primary safety and effectiveness endpoints were based on independent angiographic reviewers.

The primary safety endpoint was a composite endpoint identified by both site reported safety data (MAEs) and angiographic data (clinically significant perforations, embolizations and Grade C or greater dissections) assessed by independent angiographic reviewers. Four (4) clinically significant perforations (4.8%) occurred at the time of the procedure identified by the independent angiographic reviewers. No further sequelae were reported by any of the subjects prior to discharge. There were no occurrences of MAEs (0.0%) or unanticipated adverse events. The primary safety endpoint was met.

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The primary effectiveness endpoint, defined as successful CTO crossing by the Wildcat Catheter and subsequent guidewire positioning through the distal true lumen (confirmed by angiography), was achieved in 89.3% of subjects. The primary effectiveness endpoint was met.

In conclusion, the results of the CONNECT Study demonstrate that the Wildcat Catheter was able to successfully facilitate crossing of chronic total occlusions (CTOs) in the majority of cases where a conventional guidewire was unsuccessful.

CONCLUSION

Based on the nonclinical and clinical testing, it may be concluded that the Wildcat Catheter satisfies safety and performance requirements when used in accordance with the Instructions for Use for the indicated patient population and does not raise any issues of safety and effectiveness. The Wildcat Catheter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Avinger, Inc.
Mr. Ziad Rouag
Vice President of Clinical, Regulatory & Quality Affairs
400 Chesapeake Drive
Redwood City, CA 94063

SEP 18 2013

Re: K111338
Trade/Device Name: Wildcat Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: July 29, 2011
Received: August 1, 2011

Dear Mr. Rouag:

This letter corrects our substantially equivalent letter of August 11, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111338

Device Name: Wildcat Catheter

Indications For Use:

The Wildcat Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Wildcat Catheter is contraindicated for use in the iliac, coronary, cerebral or carotid vasculature.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111338